

Office Action Summary	Application No.	Applicant(s)	
	10/562,428	EGAN, JOSEPH STEVEN	
	Examiner	Art Unit	
	RYAN OCHYLSKI	1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 13-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☒ Claim(s) 11-12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 December 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>herewith</u> . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>31 May 2006</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Claims 1-12 in the reply filed on November, 20 2008 is acknowledged.

Drawings

2. The drawings are objected to because of the following informalities:
3. Figures 6 and 7 both contain Item 36A that is not disclosed in the specification. Additionally, on Page 21 Line 20 of the specification, there is a reference to Item 30A appearing in Figures 6 and 7, but Item 30A does not appear in Figures 6 and 7.
4. Figure 15 contains Item O that is not disclosed in the specification. Additionally, on Page 24 Line 6 of the specification, there is a reference to Item D appearing in Figure 15, but Item D does not appear in Figure 15.
5. Figure 17 contains Items 62A and 62B, neither of which is disclosed in the specification.
6. Figure 18 contains Items 63 and 64, neither of which is disclosed in the specification.
7. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure

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is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

8. Claims 11-12 are objected to because of the following informalities:
9. Regarding Claim 11, Line 3 appears to contain an unintentional repetition of "intermediate sheet" when it appears the second time.
10. Regarding Claim 12, Lines 2-3 appear to have no proper antecedent basis for there being "different weights or different weight categories" of the claimed moulded product. For the purposes of examination the "different weights or different weight categories" are assumed to reference the patients of various weight categories disclosed in Claim 1.
11. Appropriate correction is required.

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Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. Claims 1, 4-7, and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al. (US 5,192,330).

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16. Regarding Claim 1, Chang et al. teach a method of construction of a prosthesis for patients of various weight categories, said method including the steps of:

(a) impregnating non-metallic fibres in a thermosetting resin whereby said impregnated fibres are arranged to form a sheet of said fibres (Column 5 Line 48 - Column 6 Line 4);

(b) arranging fibres in an intersecting orientation (Column 5 Lines 18-29)

(c) cutting a plurality of pre-pregs from said sheet formed in step (a) (Column 5 Lines 64-68);

(d) forming layers of said pre-pregs obtained from step (c) so that said layers are arranged in stacked relationship in a mould cavity of a compression mould whereby the mould cavity ("positioned in mold 80 in the stacked configuration" Column 6 Lines 28-42) has a constant volume for each of the various weight categories (Column 1 Lines 34-61);

(e) compression moulding at elevated temperature (Column 6 Lines 42-47); and

(f) removing the prosthesis from the compression mould (Column 6 Lines 42-47, where in order to obtain the desired finish by surface finishing, the prosthesis must inherently be removed from the compression mould).

However, while Chang et al. does not explicitly teach folding the sheet by bending adjoining parts of the sheet along adjacent fold lines therebetween so that said fibres are arranged in an intersecting orientation to form a prepeg having a double layer of fibres in different planes with the fibres in each layer having a different angle of orientation to a longitudinal axis of the prepeg and then cutting a prepreg having a double layer of fibres, Chang et al. further teaches, in an analogous embodiment,

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folding the sheet by bending adjoining parts of the sheet along adjacent fold lines therebetween to form a prepreg having a double layer of fibres in different planes (Column 8 Lines 36-46) for the benefit of providing an additional layer made of continuous fiber to strengthen the prosthesis.

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to combine the two embodiments of Chang et al. for the benefit of providing an additional layer made of continuous fiber to strengthen the prosthesis.

17. Regarding Claim 4, while Chang et al. do not explicitly teach that in step (d), layers of said pre-pregs having fibres arranged in an intersecting orientation are mixed with layers of pre-pregs which have all of their fibers arranged in a latitudinal and/or longitudinal orientation, Chang et al. do teach mixing pre-pregs having fibres arranged in an intersecting orientation as applied above, mixing single layer pre-pregs having all their fibres arranged in a longitudinal orientation into a relatively intersecting configuration (Column 5 Lines 18-29), and, in an analogous embodiment, mixing single layer pre-pregs with double layer pre-pregs (Column 8 Lines 36-46) for the benefit of providing an additional layer made of continuous fiber to strengthen the prosthesis.

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to combine the two embodiments of Chang et al. for the benefit of providing an additional layer made of continuous fiber to strengthen the prosthesis.

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18. Regarding Claims 5-7, given that when stacking pre-pregs comprising a mixture of pre-pregs having fibres arranged in an intersecting orientation and pre-pregs having all of their fibers arranged in a latitudinal and/or longitudinal orientation, there are only three possible basic configurations of stacking (completely segregated, alternating, or randomly intermixed) and given that Chang et al. teaches the mixing of prepregs as applied above, it would have been obvious to a person having ordinary skill in the art at the time of the invention to try the alternating arrangements disclosed in Claims 5-7 for the benefit of optimizing the strength of the prosthesis.

19. Regarding Claim 11, Chang et al. teach that pre-pregs having fibres arranged in a longitudinal orientation are formed from an intermediate sheet which is cut at an angle of 0° for longitudinal fibres having regard to a longitudinal axis of a drum supporting the intermediate sheet (Column 5 Lines 64-68 and Figure 16 where the ends of folded fiber 328 are flat and thus cut at 0°).

20. Regarding Claim 12, Chang et al. teach that step (d) is carried out in a mould cavity having the same dimensions for different weights or different weight categories of moulded product ("positioned in mold cavity 80" Column 6 Lines 28-46).

21. Claims 2-3 and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al. (US 5,192,330) as applied to Claim 1 above, and in view of Koizumi et al. (JP 02-153938).

22. Regarding Claim 2, Chang et al. teach that step (a) includes use of a drum winding technique whereby impregnated fibers are wound onto a drum so as to provide

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an intermediate composite sheet formed of fibres supported on the drum, whereby the sheet formed by step (a) is obtained by cutting the intermediate sheet as it is supported on the drum (Column 5 Lines 62-68).

However, Chang et al. do not teach that a sheet of release paper is present between the sheet and the drum.

In analogous art pertaining to pre-preg production, Koizumi et al. teach the use of release paper when winding a prepreg onto a drum (Abstract) for the benefit of preventing pre-preg layers from sticking together thus making for a faster process.

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to combine Chang et al. with Koizumi et al. for the benefit of preventing pre-preg layers from sticking together thus making for a faster process.

23. Regarding Claim 3, Chang et al. teach that use is made of a hot melt technique wherein after hot melt resin impregnation of the fibres they are laid into a continuous sheet (Column 5 Line 68 - Column 6 Line 4).

However, Chang et al. do not teach that the sheet is laid onto a sheet of release paper or that the sheet is subsequently stored as rolls.

In analogous art pertaining to pre-preg production, Koizumi et al. (JP 02-153938) teach the use of release paper and storing the sheet as a roll ("wound by the second winder" Abstract) for the benefit of preventing pre-preg layers from sticking together thus making for a faster process and storing the sheets in a manner that does not compromise strength of the sheets, thus making for a stronger product.

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to combine Chang et al. with Koizumi et al. for the benefit of preventing pre-preg layers from sticking together thus making for a faster process and storing the sheets in a manner that does not compromise strength of the sheets, thus making for a stronger product.

24. Regarding Claims 8 and 9, Chang et al. teach that the intermediate sheet is cut (including the cut angle as illustrated by pre-preg 330 in Figure 16) and the final sheet is folded upon itself to form the pre-preg as applied above. Chang et al. further teach that the angle of orientation between layers of fibres may be up to 90° (Column 5 Lines 18-29).

However, Chang et al. do not teach cutting at a variety of different angles selected from the group consisting of 15°, 22.5°, 30°, 45°, and 60° so that the final sheet has sloping sides having an acute angle to vertical before the folding step.

In analogous art pertaining to pre-preg production, Koizumi et al. teach cutting at a variety of different angles so that the final sheet has sloping sides having an acute angle to vertical (“cutting an UD prepreg sheet to the desired fiber oriented angle” Abstract) for the benefit of increasing pliability of the sheet.

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to combine Chang et al. with Koizumi et al. for the benefit of increasing pliability of the sheet.

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25. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al. (US 5,192,330) and Koizumi et al. (JP 02-153938) as applied to Claim 2 above, and further in view of Oosedo et al. (US 2002/0007022).

26. Regarding Claim 10, the previous combination teaches cutting of the intermediate sheet at a variety of different angles selected from the group consisting of 15°, 22.5°, 30°, 45°, and 60° for pre-pregs of intersecting fibres as applied above.

However, the previous combination does not teach that the cutting is carried out by provision of cutting lines or grooves which are formed in an outer surface of the drum at an angle selected from the group consisting of 15°, 22.5°, 30°, 45°, and 60°.

In analogous art pertaining to pre-preg production, Oosedo et al. teach that cutting of pre-pregs is carried out by provision of cutting lines situated at an angle corresponding to desired angles of cutting (Figure 2 Item 8 and [0019]) for the benefit of ensuring the cuts are as accurate as possible by providing the cutting lines or grooves as guides for the cutting process, thus making the process more economically efficient by conserving material.

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to combine the previous combination with Oosedo et al. for the benefit of ensuring the cuts are as accurate as possible by providing the cutting lines or grooves as guides for the cutting process, thus making the process more economically efficient by conserving material.

Conclusion

27. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

28. Allshouse et al. (US 5,718,212) cite use of constant volume mold in the production of pre-pregs.

29. Shultz et al. (US 5,721,323) cite folding and stacking pre-pregs.

30. Winckler et al. (US 2001/0049430) cite the use of release paper in a hot-melt method for producing pre-pregs.

31. Okamoto et al. (JP 08-008109) cite a pre-preg strip tilted at a predetermined angle to the bus-line along a cylindrical circumferential surface.

32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RYAN OCHYLSKI whose telephone number is 571-270-7009. The examiner can normally be reached on Monday through Thursday and every other Friday from 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Del Sole can be reached on 571-272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

rmo

/Joseph S. Del Sole/
Supervisory Patent Examiner, Art Unit 4152